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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/904,536	07/16/2001	Thomas J. Graddis	3260.0028-01	3851
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22852 7590 01/29/2003

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WASHINGTON, DC 20006

EXAMINER

SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

Applicant(s)

Examiner

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- ☒ Responsive to communication(s) filed on 11/18/02.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- ☒ Claim(s) 33-45, 52-55 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 33-45, 52-55 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_.

### Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 3
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

**Part III: Detailed Office Action**

Claims 33-45 and 52-55 are pending.

**Restriction Requirement:**

5 Applicant's election without traverse of Group I, claims 33-45 and 52-55 as they are drawn to methods of administering protein, with an election of species of dendritic cells in Paper No. 7 filed 11/20/02 is acknowledged.

**Formal Matters:**

10 Claims 38-45 are objected to for encompassing plural, patentably distinct inventions. The claims should be amended to restrict the claimed subject matter to the elected invention, administration of protein.

✓ The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

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The disclosure is objected to because of the following informalities. Appropriate correction is required for *each* listed item:

✓ - The status of the related applications to which reference is made at page 1§1 of the specification should be updated.

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**Objections and Rejections under 35 U.S.C. §112:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

25 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-45 and 52-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention.

5 The claims are indefinite because it is not clear *of what* the soluble flt3-L used in the claimed methods is a mutant. Mutant is a relative term, and requires a 'wild type' sequence as a basis for determination that the mutant comprises a mutation. Recitation of the claim to indicate that the claimed protein is a mutated form of human flt3-L, for example, would be remedial.

**Rejections Over Prior Art:**

10 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15 (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States  
20 only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

25 Claims 33-45 and 52-55 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 5,843,423 (Lyman et al.).

30 Lyman et al. disclose and claim methods consistent with the instant claims. flt3-L variants are disclosed and discussed at columns 5 and 10-11, for example. Treatment of patients with cancer or other neoplastic diseases is found at col. 3, lines 37-43. The claimed methods include the use of additional cytokines, treatment of HIV/AIDS, and both *in vitro* and *in vivo* cell expansion. As dendritic cells are found in numerous organs, lymphoid tissues, and in peripheral blood, dendritic cells would inherently be present and thus treated in the methods of Lyman et al. Accordingly, the

pending claims are anticipated by the disclosure and claims of Lyman et al.

Claims 33-45 and 52-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Brasel et al., WO97/12633, cited by applicants.

5           Brasel et al. disclose the use of Flt3-L as a dendritic cell stimulatory factor (title, abstract).  
The disclosure includes both *in vivo* and *ex vivo* or *in vitro* methods, the use of costimulatory  
cytokines, and envisions treatment for augmentation of immune responses, including in patients with  
cancerous or neoplastic diseases or AIDS, as well as methods of enhancing autoimmune tolerance;  
see pages 3-4 and claims. Flt3-L is defined at page 4 by reference to the Lyman patent above (U.S.  
10   Patent Number 5,843,423), and thus includes the mutants and variants disclosed therein.  
Accordingly, the disclosure by Brasel et al. anticipates the claimed subject matter.

The prior art made of record and not relied upon is considered pertinent to applicant's  
disclosure.

15           Maraskovsky et al., J.Exp. Med. 184:1953 disclose that daily injection of human Flt3 ligand  
into mice results in a dramatic increase in functionally mature dendritic cells, including in spleen.  
This publication is by the same group as the Brasel publication above, and is the peer-reviewed  
report of that work.

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**Advisory Information:**

No claim is allowed.

25           Any inquiry concerning this communication or earlier communications from the Examiner should be directed  
to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday  
through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz,  
at (703)308-4623.

30           Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to  
the Group receptionist at telephone number (703) 308-0196.

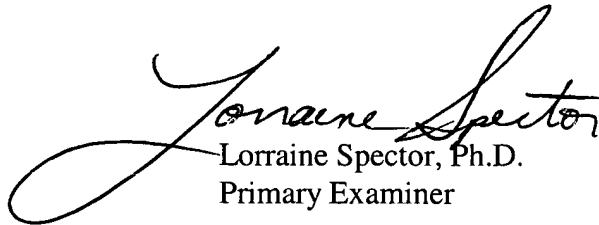
Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers

Serial Number 09/904536  
Art Unit 1647

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5 should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228.

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Lorraine Spector, Ph.D.  
Primary Examiner

09/904536.1  
1/24/03